Complete Summary

GUIDELINE TITLE

Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management.

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology 2004 Jun;100(6):1573-81. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Subsequently, on April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of

prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute perioperative pain

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Anesthesiology
Geriatrics
Internal Medicine
Pediatrics
Surgery

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

To (1) facilitate the safety and effectiveness of acute pain management in the perioperative setting; (2) reduce the risk of adverse outcomes; (3) maintain the patient's functional abilities, as well as physical and psychological well-being; and (4) enhance the quality of life for patients with acute pain during the perioperative period

TARGET POPULATION

Adult (including geriatric) and pediatric patients undergoing either inpatient or outpatient surgery

Excluded populations: Patients with severe or concurrent medical illness such as sickle cell crisis, pancreatitis, or acute pain related to cancer or cancer treatment; patients with labor pain

INTERVENTIONS AND PRACTICES CONSIDERED

1. Development of institutional policies and procedures for perioperative pain management
    - Education and training of healthcare providers and patients
    - Monitoring and documentation of data
    - Monitoring of institutional patient outcomes
    - Availability (24 hours) of anesthesiologists
    - Use of dedicated acute pain service
2. Preoperative patient evaluation
    - Pain history
    - Physical exam
    - Development of a pain control plan
3. Preoperative preparation
    - Adjustments and/or continuation of medications
    - Initiation of postoperative pain management therapy
    - Patient education for patient controlled analgesia (PCA)
4. Perioperative pain management
    - Epidural or intrathecal opioid analgesia (morphine, fentanyl)
    - Patient-controlled analgesia with systemic opioids (morphine)
    - Regional techniques (peripheral nerve blocks, postincisional infiltration with local anesthetics)
    - Multimodal techniques for pain management: nonsteroidal anti-inflammatory drugs (NSAIDs); cyclooxygenase-2 inhibitors (COXIBs); acetaminophen
5. Special considerations for patient subpopulations
    - Care of pediatric patients
    - Care of geriatric patients
    - Care of other patient groups (patients who are critically ill, cognitively impaired (e.g., Alzheimer's disease), or who otherwise have difficulty communicating (e.g., cultural or language barriers)

MAJOR OUTCOMES CONSIDERED

- Effectiveness of acute pain management
- Risk of adverse outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Scientific evidence was derived from aggregated research literature, and from surveys, open presentations, and other consensus-oriented activities (e.g., Internet posting). For purposes of literature aggregation, potentially relevant clinical studies were identified via electronic and manual searches of the literature. The electronic search covered a 38-year period from 1966 through 2003. The manual search covered a 42-year period from 1952 through 2003. More than 4,000 citations were initially identified, yielding a total of 1,695 nonoverlapping articles that addressed topics related to the evidence linkages. After review of the articles, 1,067 studies did not provide direct evidence and were subsequently eliminated. A total of 628 articles contained direct linkage- related evidence.

NUMBER OF SOURCE DOCUMENTS

A total of 628 articles contained direct linkage-related evidence.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

When sufficient numbers of studies are available for evaluation, the following terms describe the strength of the findings.

Supportive: Meta-analyses of a sufficient number of adequately designed studies indicate a statistically significant relationship ($P<0.01$) between a clinical intervention and a clinical outcome.

Suggestive: Information from case reports and descriptive studies permits inference of a relationship between an intervention and an outcome. This type of qualitative information does not permit a statistical assessment of significance.

Equivocal: Qualitative data are not adequate to permit inference of a relationship between an intervention and an outcome and (1) there is insufficient quantitative information, or (2) aggregated comparative studies have found no significant differences among groups or conditions.

The lack of scientific evidence in the literature is described by the following terms.

Silent: No identified studies address the relationship of interest.

Insufficient: There are too few published studies to investigate a relationship between an intervention and an outcome.

Inadequate: The available studies cannot be used to assess the relationship between an intervention and an outcome. These studies either do not meet the criteria for content as defined in the "Focus" of these Guidelines, or they do not permit a clear causal interpretation of findings because of methodologic concerns.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The scientific assessment of these Guidelines was based on evidence linkages or statements regarding potential relationships between clinical interventions and outcomes. The interventions were examined to assess their relationship to a variety of outcomes related to the management of acute pain in the perioperative setting.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment for each linkage prior to conducting formal meta-analysis. Literature pertaining to 15 evidence linkages contained enough studies with well-defined experimental designs and statistical information sufficient for meta-analyses. These linkages were (1) acute pain service, (2) patient and family education, (3) epidural or intrathecal opioids, (4) intravenous patient-controlled analgesia (PCA) versus nurse-controlled or continuous intravenous, (5) intravenous PCA versus intramuscular, (6) epidural PCA versus intravenous PCA, (7) intravenous PCA with background infusion of opioids versus no background infusion, (8) intercostal or interpleural blocks, (9) plexus and other blocks, (10) infiltration of incisions, (11) epidural opioids combined with local anesthetics versus epidural opioids, (12) epidural opioids combined with local anesthetics versus epidural local anesthetics, (13) epidural opioids combined with clonidine versus epidural opioids, (14) intravenous opioids combined with ketorolac versus intravenous opioids, and (15) intravenous opioids combined with ketamine versus intravenous opioids.

General variance-based effect-size estimates or combined probability tests were determined for continuous outcome measures, and Mantel- Haenszel odds-ratios were determined for dichotomous outcome measures. Two combined probability tests were employed as follows: (1) The Fisher combined test, producing chi-square values based on logarithmic transformations of the reported P values from the independent studies; and (2) the Stouffer combined test, providing weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using 2X2 tables was used with outcome frequency information. An acceptable significance level was set at $P<0.01$ (one-tailed). Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. DerSimonian-Laird random-effects odds ratios were considered when significant heterogeneity was found. To control

for potential publishing bias, a "fail-safe n" value was calculated. No search for unpublished studies was conducted, and no reliability tests for locating research results were performed.

Meta-analytic results are reported in Table 1 of the original guideline document. To be considered acceptable findings of significance, Mantel-Haenszel odds-ratios must agree with combined test results when both types of data are assessed. In the absence of Mantel-Haenszel odds-ratios, both the Fisher and weighted Stouffer combined test results must agree with each other to be considered acceptable findings of significance.

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa statistic for two-rater agreement pairs were as follows: (1) type of study design, kappa = 0.63 to 0.94; (2) type of analysis, kappa = 0.39 to 0.89; (3) evidence linkage assignment, kappa = 0.74 to 0.96; and (4) literature inclusion for database, kappa = 0.75 to 0.88. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.80, Var (Sav) = 0.007; (2) type of analysis, Sav = 0.59, Var (Sav) = 0.032; (3) linkage assignment, Sav = 0.73 Var (Sav) = 0.010; (4) literature database inclusion, Sav = 0.83 Var (Sav) = 0.015. These values represent moderate levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members after considering opinions derived from a variety of sources, including informal commentary and comments from postings of the draft document on the American Society of Anesthesiologists (ASA) Web site. In addition, opinions obtained from consultant surveys, open forum commentary and other sources used in the original Guidelines were reviewed and considered.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society of Anesthesiologists (ASA) appointed a Task Force of nine members to (1) review the published evidence, (2) obtain the opinions of anesthesiologists selected by the Task Force as consultants, and (3) build consensus within the community of practitioners likely to be affected by the Guidelines. The Task Force included anesthesiologists in both private and academic practices from various geographic areas of the United States, and consulting methodologists from the ASA Committee on Practice Parameters.

These Guidelines update the 1995 publication of Practice Guidelines for Acute Pain Management in the Perioperative Setting. The Task Force revised the earlier Guidelines by reviewing and evaluating original published research studies retrieved from multiple sources.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document was made available for review on the American Society of Anesthesiologists (ASA) Web site, and input was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Institutional Policies and Procedures for Providing Perioperative Pain Management

Anesthesiologists offering perioperative analgesia services should provide, in collaboration with other healthcare professionals as appropriate, ongoing education and training to ensure that hospital personnel are knowledgeable and skilled with regard to the effective and safe use of the available treatment options within the institution. Educational content should range from basic bedside pain assessment to sophisticated pain management techniques (e.g., epidural analgesia, patient controlled analgesia, and various regional anesthesia techniques) and nonpharmacologic techniques (e.g., relaxation, imagery, hypnotic methods). For optimal pain management, ongoing education and training are essential for new personnel, to maintain skills, and whenever therapeutic approaches are modified.

Anesthesiologists and other healthcare providers should use standardized, validated instruments to facilitate the regular evaluation and documentation of pain intensity, the effects of pain therapy, and side effects caused by the therapy.

Analgesic techniques involve risk for adverse effects that may require prompt medical evaluation. Anesthesiologists responsible for perioperative analgesia should be available at all times to consult with ward nurses, surgeons, or other involved physicians, and should assist in evaluating patients who are experiencing problems with any aspect of perioperative pain relief.

Anesthesiologists providing perioperative analgesia services should do so within the framework of an Acute Pain Service, and participate in developing

standardized institutional policies and procedures. An integrated approach to perioperative pain management that minimizes analgesic gaps includes ordering, administering, and transitioning therapies, and transferring responsibility for perioperative pain therapy, as well as outcomes assessment and continuous quality improvement.

Preoperative Evaluation of the Patient

A directed pain history, a directed physical examination, and a pain control plan should be included in the anesthetic preoperative evaluation.

Preoperative Preparation of the Patient

Patient preparation for perioperative pain management should include appropriate adjustments or continuation of medications to avert an abstinence syndrome, treatment of preexistent pain, or preoperative initiation of therapy for postoperative pain management.

Anesthesiologists offering perioperative analgesia services should provide, in collaboration with others as appropriate, patient and family education regarding their important roles in achieving comfort, reporting pain, and in proper use of the recommended analgesic methods. Common misconceptions that overestimate the risk of adverse effects and addiction should be dispelled. Patient education for optimal use of patient-controlled analgesia (PCA) and other sophisticated methods, such as patient-controlled epidural analgesia (PCEA), might include discussion of these analgesic methods at the time of the preanesthetic evaluation, brochures, and videotapes to educate patients about therapeutic options, and discussion at the bedside during postoperative visits. Such education may also include instruction in behavioral modalities for control of pain and anxiety.

Perioperative Techniques for Pain Management

Anesthesiologists who manage perioperative pain should utilize therapeutic options such as epidural or intrathecal opioids, systemic opioid PCA, and regional techniques, after thoughtfully considering the risks and benefits for the individual patient. These modalities should be used in preference to intramuscular opioids ordered "as needed." The therapy selected should reflect the individual anesthesiologist's expertise, as well as the capacity for safe application of the modality in each practice setting. This capacity includes the ability to recognize and treat adverse effects that emerge after initiation of therapy. Special caution should be taken when continuous infusion modalities are used, as drug accumulation may contribute to adverse events.

Multimodal Techniques for Pain Management

Whenever possible, anesthesiologists should employ multimodal pain management therapy. Unless contraindicated, all patients should receive an around-the-clock regimen of non-steroidal anti-inflammatory drugs (NSAIDs), cyclooxygenase-2 inhibitors (COXIBs), or acetaminophen. In addition, regional blockade with local anesthetics should be considered. Dosing regimens should be administered to optimize efficacy while minimizing the risk of adverse events. The

choice of medication, dose, route, and duration of therapy should be individualized.

Patient Subpopulations

Pediatric Patients

Aggressive and proactive pain management is necessary to overcome the historic undertreatment of pain in children. Perioperative care for children undergoing painful procedures or surgery requires developmentally appropriate pain assessment and therapy. Analgesic therapy should depend on age, weight, and comorbidity, and unless contraindicated should involve a multimodal approach. Behavioral techniques, especially important in addressing the emotional component of pain, should be applied whenever feasible.

Sedative, analgesic, and local anesthetics are all important components of appropriate analgesic regimens for painful procedures. As many analgesic medications are synergistic with sedating agents, it is imperative that appropriate monitoring be employed during the procedure and recovery.

Geriatric Patients

Pain assessment and therapy should be integrated into the perioperative care of geriatric patients. Pain assessment tools appropriate to a patient's cognitive abilities should be employed. Extensive and proactive evaluation and questioning may be necessary to overcome barriers that hinder communication regarding unrelieved pain. Anesthesiologists should recognize that geriatric patients might respond differently than younger patients to pain and analgesic medications, often because of comorbidity. Vigilant dose titration is necessary to ensure adequate treatment while avoiding adverse effects such as somnolence in this vulnerable group, who are often taking other medications (including alternative and complementary agents).

Other Groups

Anesthesiologists should recognize that patients who are critically ill, cognitively impaired, or have communication difficulties may require additional interventions to ensure optimal perioperative pain management. Anesthesiologists should consider a therapeutic trial of an analgesic in patients with elevated blood pressure and heart rate or agitated behavior, when causes other than pain have been excluded.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Scientific evidence was derived from multiple sources, including aggregated research literature (with meta-analyses when appropriate), surveys, open presentations, and other consensus-oriented activities. The findings of the literature analyses were supplemented by the opinions of Task Force members and surveys of the opinions of a panel of consultants.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Adequately controlled pain and prevention of adverse outcomes that may result from the undertreatment of perioperative pain, including (but not limited to), thromboembolic and pulmonary complications, additional time spent in an intensive care unit or hospital, hospital readmission for further pain management, needless suffering, impairment of health-related quality of life, and development of chronic pain

POTENTIAL HARMS

Adverse outcomes associated with the management of perioperative pain include (but are not limited to) respiratory depression, brain or other neurologic injury, sedation, circulatory depression, nausea, vomiting, pruritus, urinary retention, impairment of bowel function, and sleep disruption.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints.
- Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.
- Modalities for perioperative pain management addressed in these Guidelines require a higher level of professional expertise and organizational structure than as needed intramuscular or intravenous injections of opioid analgesics. These Guidelines are not intended as an exhaustive compendium of specific techniques.
- While patients undergoing painful procedures may benefit from the appropriate use of anxiolytics and sedatives in combination with analgesics and local anesthetics when indicated, these Guidelines do not specifically address the use of anxiolysis or sedation during such procedures.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force on Acute Pain Management. Practice guidelines for acute pain management in the perioperative setting: an updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology 2004 Jun;100(6):1573-81. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jun

GUIDELINE DEVELOPER(S)

American Society of Anesthesiologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Anesthesiologists

GUIDELINE COMMITTEE

Task Force on Acute Pain Management

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Anesthesiologists Web site.

Print copies: Available from the American Society for Anesthesiologists, 520 North Northwest Highway, Park Ridge, IL 60068-2573.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 13, 2005. The information was verified by the guideline developer on July 20, 2005.

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Date Modified: 9/25/2006